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| 10/821,732 | 04/08/2004 | Yasuyuki Kawashima | 11333/38 | 1524 |
| 757 7590 06/17/2010 BRINKS HOFER GILSON & LIONE P.O. BOX 10395 CHICAGO, IL 60610 | | | | |
| EXAMINER | | | | |
| SRIVASTAVA, KAILASH C | | | | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/821,732

Applicant(s)

KAWASHIMA, YASUYUKI

Examiner

Kailash C. Srivastava

Art Unit

1657

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 March 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11, 14-21, 25 and 26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11, 14-21, 25 and 26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB-06)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

1. Response and amendment filed 25 March 2010 to the Non-Final Office Action mailed 28 September 2009 is acknowledged and entered.

Claims Status

2. Claims 12-13 have currently been cancelled. Claims 1-10, 22-24 and 27 have previously been cancelled.
3. Claims 11, 14, 19, 21, 25 and 26 have currently been amended.
4. Claims 11, 14-21 and 25-26 are currently pending and are examined on merits.

Informal Matters

5. The indication for the support to the Claim amendments filed 25 March 2010 has not been indicated in the Remarks filed 25 March 2010 (See Page 5, Line 1 to Page 9, Line 7). However, to expedite the prosecution of the instant application, the Office Action follows.
6. Applicant's comments with respect to the waiver of Appeal, or Applicant's statutory rights (See Remarks filed 25 March 2010, Page 5, Lines 9-11), Examiner has only stated the facts that were discussed during the interview of 09 February 2009 and re-iterated Applicants' remarks filed 07/13/2009 that Applicant has stated on record that said point is moot (See remarks filed 07/13/2009, Page 5, Line 16). As Examiner stated in the Office Action mailed 28 September 2009 (Page 2, item 4, Lines 1-6), the Examiner stands corrected and the record is clear in this regard.

Withdrawn Rejections

7. Considering the Amendments and remarks filed 25 March 2010, the Obviousness rejection to Claims 11-21 and 25-26 under 35 U.S.C. § 103(a) over combined teachings from Wallner et al (1997. Flow Sorting of Microorganisms for Molecular Analysis Applied and Environmental Microbiology, Volume 63, 223-4231) and Fukuda et al (US Patent 6,165,740, issued 26 Dec 2000) in view of Kubitschek et al (1986. Determination of Bacterial Cell Volume with the Coulter Counter. Journal of Bacteriology Volume 168, Pages 1466-1467) and further in view of Chupp et al (US Patent 5,631,165) in the Office Action mailed 28 September 2009 is hereby withdrawn.

Claim Objections

8. Claims 11 and 25 each are objected to because the limitation, “a memory storing programs for enabling the processor” at Line 9 of each of the Claims is grammatically awkward. Appropriate correction is required.

Claim Rejections – 35 U.S.C. § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. §102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 11, 14-17 and 25 are rejected under 35 U.S.C. §102(b) as anticipated by Wallner et al (1997, Flow Sorting of Microorganisms for Molecular Analysis Applied and Environmental Microbiology, Volume 63, Pages 4223–4231).

In response filed 25 March 2010, assertion is made that rejection of Claims 11-17 and 25 as anticipated by Wallner et al., is overcome “in view of the amendment of Claims 11 and 25 together with the remarks” presented and “Wallner et al., do not suggest or disclose a bacteria measuring apparatus configured as recited by Claim 25” (See remarks filed 25 March 2010, Page 5, Lines 13-31, Page 6, Lines 4-33 and Page 7, Lines 4-5).

Claims 11-17 and 25 are drawn to an apparatus (i.e., device or a machine) having components:

- Sampling device, first detector, second detector, processor, memory (currently amended Claims 11 and 25);
- A member having a pore (Claim 16);
- Flow cell (Claim 17);

Wallner et al., teach a flow cytometer (i.e., FACStar Plus cell sorter) equipped with a sampling component, detectors (Page 4224, Lines 41-59) and said equipment (i.e., FACStar Plus cell sorter) is additionally equipped with a video monitor (i.e., a display) a computer system and software and an internal 3.5” floppy drive. (See, B-D FACStar Plus Cell Sorter Flow Cytometer at <http://www.biomedika.com> Tue Apr 23 16:51:45 EST 2002).

Thus, said flow cytometer comprises the components:

sampling device, first i.e., the floppy disc drive and software), a member having a pore, Flow cell inherent to flow cytometers because that is how the detectors would detect the material passing through) and a display (i.e., the Video monitor, See Line 18 of the biomedika.com brochure);

that are currently claimed in amended Claims 11, 19, 25 and in Claims 16-17.

Please note the descriptions in remainder of Claim 11 and Claims 14-15 recites functional intended use of the apparatus components claimed in Claims, 11, 16-17 and 25) and therefore, do not carry any patentable weight because the functional intended use does not change in any shape or form the configuration or functionality for said apparatus or components thereof. However, Wallner et al's apparatus/device must function as instantly claimed because said prior art apparatus/device is comprised of same components and is being applied for the same intended functional use as the claimed apparatus (See e.g., *In re Best*, 195 USPQ 430, 433-CCPA 1977). Note further, that Wallner et al., also teach the functional intended use of said components ((Page 4224, Column 1, Lines 40-63) and further teach the same description regarding bacteria as instantly claimed. Wallner et al., additionally teach bacterial counting, size distribution, scattergram in a straight line and further a distinction between bacilli and cocci type bacterial morphologies (Figures 1-2, 4 and Table 2). Therefore, Wallner et al., reference is deemed to anticipate the cited claims.

Another assertion is made with respect to the mechanism of analysis of the claimed apparatus that has been described in the specification (See remarks filed 25 March 2010, Page 5, Lines 15-24).

First of all, the subject matter discussed at remarks filed 25 March 2010, Page 5, Lines 15-24 has not been claimed in the currently presented Claims 11, 14-21 and 25-26. Secondly said discussion is regarding the functional mechanism of the apparatus, which does not carry any patentable weight because it does not change the apparatus *per-se*. Furthermore, the invention is what is claimed in the claims and **although claims are interpreted in light of the specification, critical limitations from the specification cannot be read into the claims** (see, e.g., *In re Van Guens*, 988 F.2d 1181, 26 PSPG2d 1057 (DED. Cir. 1991).

Applicants' arguments filed 25 March 2010 regarding the rejection to Claims 11-17 and 25 under 35 U.S.C. §102(b) as anticipatory by Wallner et al (1997. Flow Sorting of Microorganisms for Molecular Analysis Applied and Environmental Microbiology, Volume 63, Pages 4223-4231) in the Office Action mailed 28 September 2009 have been fully and carefully considered but are not persuasive for the reasons of record at pages 3-4, item 12 in said Office Action, and those discussed *supra*. Thus, the rejection of

Claims 11, 14-17 and 25 under 35 U.S.C. §102(b) as anticipatory by Wallner et al (1997 is reaffirmed. Flow Sorting of Microorganisms for Molecular Analysis Applied and Environmental Microbiology, Volume 63, Pages 4223-4231) in the Office Action mailed 28 September 2009 is maintained and adhered to.

11. Claims 11, 14-15, 17, 19, and 25 are rejected under 35 U.S.C. 102(b) as anticipated by Fukuda et al (US Patent 6,165,740 A).

In response filed 25 March 2010, assertion is made that rejection of Claims 11-15, 17, 19, and 25 as anticipated by Fukuda et al., is overcome “in view of the amendment of Claims 11 and 25 together with the remarks” presented and “Claims 11, 14-15, 17 and 19 are allowable” (See remarks filed 25 March 2010, Page 7 Lines 6-28 and Page 5, Lines 13-31, Page 6, Lines 4-33 and Page 7, Lines 4-5 for reference) .

Claims 11, 14-15, 17, 19 and 25 are drawn to an apparatus (i.e., device or a machine) having components:

- Sampling device, first detector, second detector, processor, memory (currently amended Claims 11 and 25);
- Flow cell (Claim 17);
- Display (currently amended Claim 19);

Fukuda et al., teach a flow cytometer having a sample receptacle, detectors signal processing unit, a flow cell, memory and a display (Column 6, Lines 25-25; Column 7, Lines 7-67 and Column 8, Line 1, Figs 1-3). Fukuda et al., also teach forward scatter light and fluorescent light detection (Column 6, Lines 43-45) and analysis of data as well as scattergram preparation from said analysis (Column 6, Lines 55-69). Thus, Fukuda et al., teach each and every element presented in amended Claims 11, 19, 25 and in Claims 14-15 and 17). In addition discussion regarding functional intended use of a device presented *supra* in item 10 with respect to anticipatory rejection by Wallner et al., is also applicable with respect to rejection of Claims 11, 14-15, 17, 19, and 25. Therefore, Fukuda et al., reference is deemed to anticipate the cited claims.

Applicants’ arguments filed 25 March 2010 regarding the rejection to Claims 11, 14-15, 17, 19 and 25 under 35 U.S.C. §102(b) as anticipatory by Fukuda et al (US Patent 6,165,740 A) in the Office Action mailed 28 September 2009 have been fully and carefully considered but are not persuasive for the

reasons of record at page 5, item 13 in said Office Action, and those discussed *supra*. Thus, the rejection of Claims 11, 14-15, 17, 19 and 25 under 35 U.S.C. §102(b) as anticipatory by Fukuda et al (US Patent 6,165,740 A) in the Office Action mailed 28 September 2009 is maintained and adhered to.

Claim Rejections - 35 U.S.C. § 103

12. In view of the amendment filed 25 March 2010, the following is a new rejection under 35 U.S.C. §103(a).

13. The following is a quotation of 35 U.S.C. §103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

14. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. § 103(c) and potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103(a).

15. Claims 11,14-21 and 25-26 are newly rejected under 35 U.S.C. § 103(a) as obvious over combined teachings from Wallner et al (1997. Flow Sorting of Microorganisms for Molecular Analysis Applied and Environmental Microbiology, Volume 63, 223-4231) and Fukuda et al (US Patent 6,165,740, issued 26 Dec 2000) in view of Dow et al (1979. Particle size distribution analysis for the rapid detection of microbial infection of urine. Journal of Clinical Pathology, Volume 32, Pages 386-390).

Claims 11,14-21 and 25-26 recite an apparatus to measure bacteria, said apparatus comprising a sampling device, a first detector, a second detector, and a control unit. Said apparatus further comprises a display unit.

Regarding Claims 11,14-21 and 25-26, teachings from Wallner et al., and Fukuda et al., respectively have been discussed at items 10-11 *supra*. Wallner et al., further describe that DAPI fluorescence was measured and additionally show different bacterial morphologies (i.e., cocci and bacilli measured as well as the non-measured bacteria (Table 1) Thus, Wallner et al., teach warning when the

cells are not sorted. Despite teaching the measurement for DAPI fluorescence, Wallner et al., are silent regarding the specimen holding, reagent holding and reagent mixing parts as well as the reliability of results and clearly about the pore.

Fukuda et al., teach a specimen holding, a reagent holding and mixing part because they teach that the specimen is en-sheathed with a sheath liquid (Column 6, Lines 37-40). Fukuda et al., additionally teach the limitations claimed in Claim 21 despite said claim limitation referring to functionality of a particular component of the instantly claimed apparatus and accordingly not carrying patentable weight. This is because Fukuda et al., teach accuracy of results (Column 4, Lines 43-44; Column 7, Lines 35-37) and distinguishing bacterial/microbiological cellular morphologies- displaying scattergrams (Figures 6-28) and further showing that said morphologies are distinct from each other with further analysis of different scattergrams (Figure 29).

Dow et al., teach a Coulter counter equipped with an orifice probe and a Channelyzer (Page 387, Column 1, Lines 9-25; Figure 1; Figure 2 and Page 387, Column 2 Lines 1-9 under Figure 2). The specimen mixed with a reagent (isoton) passes through the 30 μ m orifice and the created voltage pulse because of the passage of the particle (i.e., bacterium), said voltage pulse signal analyzed by the Channelyzer to produce an XY plot of cell volume verses relative cell number Figures 1 and 3-4). Dow et al., further teach that particle size distribution profiles can be further analyzed by a computer to make a diagnosis (Page 390, Column 1, Lines 21-26). Thus, Dow et al., teach specimen holding, reagent holding and remixing parts, along with the "pore member" through which the sample passes and additionally processing, analysis and display of the information of analysis because the Channelyzer receives the signal, analyzes the data and presents as an X-Y plot.

Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to arrange a single apparatus for determining bacterial morphological species by combining an impedance analyzer with an optical flow cytometer as is taught by the combining teachings from Wallner et al., Fukuda et al., and Dow et al., discussed *supra*; because Fukuda et al. teach a flow cytometer that scatters light in different planes, said detected light is processed, analyzed and displayed as scattergram distinguishing cocci and bacilli type bacterial morphologies, said apparatus determines volume of the aggregates, further teaches the reliability of the results and Dow et al., teach a pore member through which the samples pass in a single apparatus.

Thus, a person of ordinary skill in the art at the time the invention was made would have been motivated to arrange an apparatus comprising an optical cytometer and a Coulter impedance counter

according to the combined teachings from Wallner et al., Fukuda et al., and Dow et al.; because Fukuda et al. teach a flow cytometer that scatters light in different planes distinguishing cocci and bacilli type bacterial morphologies, said apparatus determines volume of the aggregates, and Dow et al., teach a pore member through which the samples pass in a single apparatus.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

16. Applicants' amendment filed 25 March 2010 necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

17. For the aforementioned reasons, no claims are allowed.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Kailash C. Srivastava whose telephone number is (571) 272-0923. The examiner can normally be reached on Monday to Thursday from 7:00 A.M. to 5:30 P.M. (US Eastern Standard or Daylight Savings Time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached at (571)-272-0925 Monday through Thursday 7:30 A.M. to 6:00 P.M. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding may be obtained from the Patent Application Information Retrieval (i.e., PAIR) system. Status information for the

published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (i.e., EBC) at: (866)-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kailash C Srivastava/
Examiner, Art Unit 1657

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05 June 2010

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